UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

SAJ DISTRIBUTORS, INC. and STEPHEN L. LaFRANCE HOLDINGS, INC., individually and on behalf of all others similarly situated	:	Civil Action No.
Plaintiffs,	:	
v.	:	CLASS ACTION COMPLAINT
SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE	:	
Defendant.	:	JURY TRIAL DEMANDED

CLASS ACTION COMPLAINT

1. Plaintiffs, SAJ Distributors, Inc. and Stephen L. LaFrance Holdings, Inc., bring this class action on behalf of all persons and entities who purchased the prescription medication Wellbutrin SR directly from Defendant in the United States during the period from January 24, 2002 to a date to be determined under Section 2 of the Sherman Act, 15 U.S.C. §2 (the "Class Period").

2. Wellbutrin SR is the trade name of the drug bupropion hydrochloride in a certain sustained release tablet. Wellbutrin SR is a prescription antidepressant. As with other antidepressants, the exact mechanism of Wellbutrin SR is unknown, however it is

recognized as weakly inhibiting the neuronal uptake of three neurotransmitters that have been implicated in clinical depression: norepinephrine, serotonin, and dopamine.

3. Sustained release bupropion is also marketed under the trade name Zyban. Zyban is indicated for smoking cessation. As used in this complaint, the term "Wellbutrin SR" includes both Wellbutrin SR and Zyban unless otherwise stated.

4. Plaintiffs allege Defendant has unlawfully extended its monopoly of Wellbutrin SR and its generic equivalents by making fraudulent assertions to the United States Patent and Trademark Office ("PTO") during patent prosecution and by initiating sham litigation based on: 1) invalid patents and 2) baseless allegations of infringement under the Doctrine of Equivalents. This sham litigation was intended to delay or prevent generic manufacturers from entering the market for sustained release bupropion.

5. Defendant has obtained patents based on fraudulent representations to the PTO, for products it has not invented, and patents that no reasonable patent owner would consider valid. Defendant was fully aware of the unenforceability of the patents, yet persisted in using sham litigation of these unenforceable patents to maintain its monopoly in the market for Wellbutrin SR and its generic equivalents. Defendant also engaged in sham litigation by asserting infringement under the Doctrine of Equivalents for equivalents it knowingly and purposefully disclaimed during patent prosecution. Defendant has attempted to enforce these facially over-broad and invalid patents and knowingly initiated baseless litigation no reasonable plaintiff could have expected to

win in order to prevent generic pharmaceutical companies from entering the market for sustained release bupropion in violation of the Sherman Act.

PLAINTIFFS

6. Plaintiff Stephen L. LaFrance Holdings, Inc. ("LaFrance") is a holding company with interests in retail and wholesale drug stores and distribution. LaFrance's corporate office is located in Pine Bluff, Arkansas.

7. Plaintiff SAJ Distributors, Inc. ("SAJ") is a wholly owned subsidiary of LaFrance and is LaFrance's distribution company with interests in retail and wholesale drug distribution. SAJ's corporate office is located in Pine Bluff, Arkansas. SAJ and LaFrance are the assignees of McKesson Corp., which purchased Wellbutrin SR directly from the Defendant and was injured by the illegal conduct alleged herein.

DEFENDANT

8. Defendant SmithKline Beecham Corporation, doing business as GlaxoSmithKline ("GSK"), is a Pennsylvania corporation with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania.

JURISDICTION AND VENUE

9. The Court has jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331 and 1337(a).

10. Venue is proper in this judicial district pursuant to 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c) because Defendant does business in this judicial district.

THE REGULATORY BACKGROUND FOR PRESCRIPTION DRUGS

11. The Federal Food, Drug and Cosmetic Act regulates the manufacture and distribution of drugs and medical devices in the United States, 21 U.S.C. § 301 *et seq.* Under the FDCA, premarket approval by the FDA is required before a company may begin selling a new drug, often referred to as a "pioneer" or "branded" drug, in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application ("NDA") with the FDA under § 355(b) of the FDCA, demonstrating that the drug is safe and effective for its intended use.

12. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using, offering for sale, selling or importing that new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 ("the Hatch-Waxman Act").

13. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

14. Once the NDA is approved, any claimed patents are listed with the FDA

in a publication entitled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"), where it can be easily found and consulted by future FDA applicants.

15. Pursuant to 21 U.S.C. § 355(c)(2), if a pioneer drug manufacturer is issued a new patent claiming either the drug that is the subject of an NDA or a method for its use, the company must supplement its NDA by listing such new patents within 30 days of issuance, whereupon the FDA publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true all patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information to the FDA or files frivolous patent infringement actions to delay the onset of generic competition, the FDA is powerless to stop it.

16. Once the FDA approves the safety and effectiveness of a new prescription drug, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. The pharmacist will then dispense the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as the bioequivalent of the prescription drug.

17. Generic drugs are drugs that the FDA has found to be "bioequivalent" to their corresponding brand name drug. A generic drug is bioequivalent if it provides the identical therapeutic benefits and has the same active chemical composition as its brand

name counterpart. When a generic drug is completely equivalent to a pioneer or brand name drug, the FDA assigns the generic drug an "AB" rating.

18. Generic drugs are invariably priced substantially below the branded drugs to which they are bioequivalent. Typically, the first generic drug is sold at a modest discount compared to the brand name drug, with discounts increasing, as per normal competitive dynamics, as more companies begin selling the generic. As additional generic competitors come to market, the price of the generic equivalents continues to fall, and the combined market share of the generic manufacturers continues to grow. In some cases, generic competitors sell products equivalent to brand name prescription drugs for as little as 15 percent of the price of the brand name drug, and capture as much as 90 percent of the market for that drug. Unless the branded manufacturer lowers prices to meet competition, a branded drug loses a significant portion of its market share to generic competitors less than a year after the introduction of generic competition.

19. Moreover, if a lower-priced generic version of a brand name drug exists, and the physician has not specifically indicated on the prescription "dispense as written" (or a similar instruction), and the consumer is covered by a typical third-party payor plan, the pharmacist will substitute, or at least offer to substitute, the generic drug.

20. Once a physician writes a prescription for a brand name drug such as Wellbutrin SR, that prescription defines and limits the market to the brand name drug

or its AB-rated generic equivalent. A pharmacist may substitute only drugs that carry the FDA's AB generic rating for a physician's prescription for a brand name drug.

21. Due to the nature of prescription pharmaceutical sales, the geographical market is the United States.

22. The Hatch-Waxman Amendments provide that companies may seek approval to produce and market a generic form of a previously approved, or "pioneer" drug by filing only an Abbreviated New Drug Application ("ANDA") that relies on the safety and effectiveness findings reported in the NDA for the previously approved drug.

23. The ANDA must include information concerning patents for the previously approved drug, and must include one of four certifications:

I. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");

II. that any patent listed in the FDA Orange Book for the pioneer drug has expired (a "Paragraph II Certification");

III. that the patent for the pioneer drug will expire on a particular date and the generic drug company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

IV. that the patent for the pioneer drug is invalid or will not be infringed upon by the generic drug company's proposed product (a "Paragraph IV Certification").

24. If the ANDA does not address all of the patents listed for a drug in the Orange Book by means of one of the above four certifications, the FDA will not approve the generic drug for sale.

25. If a generic company files a Paragraph IV Certification, it must promptly disclose its Paragraph IV Certification to both the NDA owner and the owner of the patent(s) at issue. Under the terms of the Hatch-Waxman Amendments, the act of filing a Paragraph IV Certification constitutes a technical act of infringement and begins a 45-day period in which a patent owner may initiate an action for patent infringement and thereby delay the FDA approval of a generic version of the NDA owner's drug. If the patent owner fails to initiate a patent infringement action within 45 days after receiving the generic manufacturer's Paragraph IV Certification the FDA may approve the generic manufacturer's ANDA. However, if the patent owner initiates an infringement action against the ANDA filer within 45 days, the FDA is statutorily prohibited from approving the ANDA until the earlier of either 30 months or a final decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

26. The Hatch-Waxman Act provides an incentive to generic pharmaceutical manufacturers to file Paragraph IV certifications challenging patents that may be invalid, not infringed by the product that is the subject of the ANDA, or unenforceable. If the applicant is the first to file an ANDA application containing a Paragraph IV challenge to a listed patent the applicant will receive a 180-day market exclusivity

period for that generic product that begins at the first commercial marketing of the generic drug unless forfeited. 21 U.S.C. 355(j)(5)(B)(iii)(IV).

THE BUPROPION PATENTS AT ISSUE

27. GSK's predecessor, Burroughs Wellcome Co., obtained U.S. Patent No. 5,427,798 on June 27, 1995 (the "'798 patent"). The '798 patent is drawn to a controlled release bupropion tablet with an enhanced shelf life.

28. GSK's predecessor, Burroughs Wellcome Co., obtained U.S. Patent No. 4,687,660 on Aug 18, 1987. That patent was reissued as U.S. Patent No. RE33,994 on July 14, 1992 (the "'994 patent"). As reissued, the patent was drawn to pharmaceutical compositions that resulted in a controlled release of bupropion in a simulated gastric buffer.

29. Upon information and belief, GSK violated its duty of candor to the United States Patent and Trade Mark Office during the prosecution of the '798 and the '994 patents by failing to disclose and/or misrepresenting to the patent examiner certain information material to the patentability of the '798 and '994 patents. Upon information and belief, GSK was aware of such information and of its materiality before the issuance of the '798 and '994 patents and that with intent to deceive, GSK withheld the information from the United States Patent and Trade Mark Office.

30. Five generic pharmaceutical companies submitted ANDAs including Paragraph IV certifications for generic Wellbutrin and all were sued by GSK for patent infringement.

THE DOCTRINE OF EQUIVALENTS

31. The Doctrine of Equivalents (DOE) prevents the unscrupulous copyist from practicing fraud on a patent by making unimportant and insubstantial changes in order to take the copied matter outside of the claim and the law.

32. The DOE roughly states that if two inventions do the same thing in the same manner to yield the same result that they are the same, even though they may differ in name, form, or shape.

33. The DOE has an important limitation in the Doctrine of Prosecution History Estoppel (also known as "File Wrapper Estoppel"), which states that a patentee is not able to use the DOE to recapture subject matter surrendered during prosecution of the patent by claiming that the surrendered material is an equivalent of the patented invention.

GSK WRONGFULLY ALLEGED INFRINGEMENT UNDER THE DOE TO ILLEGALLY DELAY GENERIC WELLBUTRIN SR FROM ENTERING THE MARKET

34. In 1993, GSK filed the application that would issue as the '798 patent.

35. During prosecution of this patent application, the patent examiner initially rejected all of the patent claims for lack of enablement noting that one of the disclosed excipients, hydroxypropyl methylcellulose ("HPMC"), is critical to the invention and should be incorporated into the independent claims.

36. An excipient is a usually inert substance used as a vehicle for a drug. In the present case, the excipients at issue also delay the release of the drug into the

gastrointestinal tract.

37. In response to the rejection, GSK submitted narrowing amendments to the patent examiner. These amendments narrowed the scope of the claims from covering all pharmaceutical means for achieving a specified release rate of bupropion to covering only HPMC, the single controlled release means divulged in the patent disclosure.

38. Hydroxypropyl cellulose ("HPC") had been recognized as a release controlling substitute excipient for HPMC since before the prosecution of the application that would issue as the '798 patent.

39. Polyvinyl alcohol ("PVA") has been known as a hydrogel material of the type that can be used to control the release of a drug such as bupropion since before the prosecution of the application that would issue as the '798 patent.

40. The Supreme Court has repeatedly held, as long ago as 1921, that the DOE cannot be used to capture subject matter disclaimed during prosecution of the patent.

41. Since 1997 the Supreme Court has twice visited the subject of how Prosecution History Estoppel should be applied, and in both cases held that a narrowing amendment made for reasons of patentability necessarily surrenders the subject matter between the non-amended and amended claims.

42. A narrow exception to Prosecution History Estoppel exists if the claimed equivalent was unforeseeable at the time of patent prosecution.

43. GSK knew that HPC was a substitute for HPMC at the time the application that would issue as the '798 patent was filed.

44. GSK also knew when the application that would issue as the '798 patent was filed that PVA could be used as a controlled release excipient.

45. On September 28, 2000, GSK initiated litigation against Impax Laboratories Inc., a generic drug manufacturer, in the United States District Court for the Northern District of California for infringing the '798 patent under the DOE for Impax's ANDA for generic Wellbutrin SR that used HPC instead of the literally claimed HPMC as the release controlling excipient (the "Impax Litigation").

46. When GSK filed the Impax Litigation, it was aware of two things: 1) at the time of filing the application that would issue as the '798 patent, HPC was a recognized substitute for HPMC; and 2) that by narrowing the patent claims during prosecution, GSK abandoned any subject matter that existed between the original and amended claims.

47. GSK, with full knowledge that no equivalents existed for the invention of the '798 patent that would cover the use of HPC as a release controlling excipient, proceeded with the baseless Impax litigation in order to invoke the 30-month FDA stay, thereby preventing a generic version of Wellbutrin SR from coming to market and consequently, illegally extending its monopoly on Wellbutrin SR and its generic equivalents while the litigation progressed.

48. On August 21, 2002, the United States District Court for the Northern District of California held in the Impax Litigation that Prosecution History Estoppel

prevented GSK from capturing HPC as an equivalent of HPMC. This ruling was upheld on appeal to the Federal Circuit on January 29, 2004.

49. On January 25, 2002, GSK brought a patent infringement suit against Excel Pharmaceuticals Inc., a generic drug manufacturer, in the United States District Court for the Eastern District of Virginia. GSK alleged that Excel was infringing the '798 patent under the DOE for its ANDA submission for generic Wellbutrin SR that used PVA instead of the literally claimed HPMC as the release controlling excipient in a bupropion compound (the "Excel Litigation").

50. When GSK filed the Excel Litigation it was aware of two things: 1) that PVA was recognized as a release controlling excipient at the time the application that would issue as the '798 patent was filed; and 2) that by narrowing the patent claims during prosecution, GSK abandoned any subject matter that existed between the original and amended claims.

51. GSK, with full knowledge that no equivalents existed for the invention of the '798 patent that would cover the use of PVA as a release controlling excipient, proceeded with the baseless Excel litigation in order to invoke the 30-month FDA stay, preventing a generic version of Wellbutrin SR from coming to market and consequently, illegally extending their monopoly on Wellbutrin SR and its generic equivalents while the litigation progressed.

52. On August 2, 2002, the United States District Court for the Eastern District of Virginia held that Prosecution History Estoppel prevented GSK from capturing PVA

as an equivalent of HPMC. This ruling was remanded for additional fact finding by the Federal Circuit on January 29, 2004, before being voluntarily dismissed under Federal Rule of Civil Procedure 41(a) by GSK on April 29, 2004.

GSK ATTEMPTS TO ENFORCE FRAUDULENT AND NONENABLED PATENTS

53. One of the requirements for the grant of a patent is that the invention must be enabled.

54. To be enabled, the patent must teach those within the relevant art how to make and use the invention in its entirety without undue experimentation.

55. The rationale underlying the enablement requirement is that in exchange for the limited monopoly one receives as a patent that the public must be taught how to make and use the invention so that upon the expiration of the patent, the public as a whole has received knowledge it otherwise would not have and can continue to make and use the invention.

56. In the '798 patent, GSK disclosed a Wellbutrin SR tablet made using a specific grade of HPMC (HPMC 2910).

57. The claims of the '798 patent were not limited to the specific grade of HPMC disclosed, and instead attempted to capture all grades of HPMC that would release Wellbutrin in a defined manner.

58. GSK brought suit against two companies, Andrx Pharmaceuticals Inc. ("Andrx") and EON Labs Manufacturing Inc. ("EON") for patent infringement in response to the filing of Paragraph IV certifications by these companies stating that the

use of another grade of HPMC did not infringe the '798 patent or that the patent was invalid.

59. On February 28, 2002, the United States District Court for the Southern District of Florida granted Andrx summary judgment that the patent was limited to the specific grade of HPMC in the specification and was not infringed by the Andrx ANDA.

60. GSK appealed the summary judgment grant to the United States Court of Appeals for the Federal Circuit. On September 22, 2003 the Federal Circuit held that the patent was not limited to the specific grade of HPMC described in the specification and the grant of summary judgment was vacated and remanded.

61. On August 22, 2003, the United States District Court for the Southern District of New York denied EON summary judgment that the patent was invalid for claiming more than was described in the specification.

62. In May of 2004, without receiving payment of any kind from the defendant, Andrx, GSK dismissed the lawsuit with Andrx.

63. In addition to the above claims, GSK's '798 patent claimed a bupropion containing tablet with a shelf life of at least one year.

64. The written description of the '798 patent divulged bupropion compounds containing HPMC with or without either cysteine hydrochloride or glycine hydrochloride.

65. It was left unclear from the patent if HPMC by itself was responsible for the extended shelf life, or if the stability was a function of either cysteine hydrochloride

or glycine hydrochloride being used in conjunction with HPMC. Neither the written description nor the claims of the '798 patent described how the shelf life stability was accomplished.

66. One wishing to use the invention after expiration of the patent would have not learned from the patent what variables, if any, were critical in stabilizing the bupropion.

67. By failing to teach those in the proper field of art how to create a bupropion tablet with the shelf life claimed in the '798 patent, GSK taught nothing to the public in exchange for the grant of the patent.

68. GSK purposefully obfuscated the patent during prosecution in an attempt to obtain patent protection without teaching the public how to practice the invention in order to prevent generic drug manufacturers from practicing the invention upon the patent's expiration.

69. On July 26, 2000, EON Labs Manufacturing Inc. ("EON"), a generic drug manufacturer, submitted an ANDA for generic Wellbutrin SR containing a Paragraph IV certification that the '798 patent was invalid or not infringed by the EON compound.

70. On November 29, 2000, GSK filed suit against Eon in the United States District Court for the Southern District of New York for infringing the '798 patent by submitting the ANDA for generic Wellbutrin SR (the "EON I Litigation").

71. By initiating this litigation, GSK received the 30-month stay preventing EON from marketing generic Wellbutrin SR.

72. On January 24, 2002, EON received tentative approval for the generic Wellbutrin SR ANDA submitted on July 26, 2000.

73. The grant of tentative approval indicated that EON would have received final approval to begin marketing of generic Wellbutrin SR if not for the legal impediment of the then outstanding GSK litigation.

74. On August 22, 2003 the United States District Court for the Southern District of New York declared claim 1 of the '798 patent invalid for lack of enablement.

75. GSK not only knew at the onset of the EON I litigation that the '798 patent was nonenabled and therefore unenforceable, but in fact had written and prosecuted the patent in such a way as to yield nothing to the public in exchange for the grant of a patent. GSK, however, still attempted to assert the invalid '798 patent in order to invoke the 30-month FDA stay, preventing a generic version of Wellbutrin SR from coming to market and consequently, illegally extending their monopoly on Wellbutrin SR and its generic equivalents.

76. GSK has also fraudulently misrepresented facts material to patentability to the PTO to obtain the '994 patent.

77. The '994 patent is a reissue patent of U.S. Patent 4,687,660 (the "'660 patent").

78. A reissue patent examination is conducted when requested by the patent holder to remedy a defect in the patent that makes it fully or partially inoperative or invalid.

79. A patent reexamination may be requested by anyone that submits prior art published materials that are material to patentability.

80. Prior to the initiation of the reissue examination, the '660 patent was being reexamined in response to the discovery of two prior art patents that, when combined, made the invention of the '660 patent obvious and unpatentable.

81. To request a reissue examination, the patent holder must assert not only that there was an error made during prosecution of the patent that makes it fully or partially inoperative or invalid, but also must specifically indicate the exact error.

82. The error alleged by the patent holder to support the reissue application was that the original patent failed to address the highly desired claims of a sustained release bupropion compound.

83. The '660 patent as issued gave two examples of a bupropion containing pill and one of a psuedoephedrine containing sustained release compound and the claims would have encompassed sustained release bupoprion without it needing to be specifically claimed.

84. The patentee realized during the reexamination proceeding that the '660 patent would most likely be held invalid over the newly discovered prior art.

85. To save some of the patent coverage that was in the original patent, the patentee conjured a story that somehow the highly desired claims to a controlled release bupropion had been omitted and that this omission went unnoticed for nearly two years, even though for almost all of this two year period the patent had been involved

in a reexamination.

86. Claims to a controlled release pseudoephedrine compound, also described in the '660 patent specification, were not prosecuted.

87. During the reissue procedure, the patentee decided that the claims that had issued in the '660 patent, and that were also at issue in the reexamination, were no longer of interest and cancelled all of them, electing to concentrate on the newly discovered claims that were alleged to have been accidentally omitted.

88. If it was not for this fraudulent, revisionist view of what the '660 patent was intended to claim there would have been no issuance of the '994 patent.

89. Not only is the '994 patent invalid for being fraudulently obtained, but it is also invalid for being nonenabled.

90. A related type of enablement issue occurs when a patent attempts to capture all means of accomplishing the goal of the invention but only divulges a limited number of examples of how to practice the invention. These are called genus/species issues since a number of species are described but a wider genus is claimed. Although these types of claims are not *per se* improper, in order to capture a genus in this manner the patentee must ensure that enough species are divulged and that the members of the genus behave similarly so that accurate predictions could be made as to how other similar species would react if used in the manner divulged.

91. GSK's '994 patent disclosed two Wellbutrin-containing "sustained release" formulations but attempted to capture all pharmaceutical compositions that

caused the release of bupropion from a tablet in a defined manner.

92. Chemistry in general, and pharmaceutical chemistry in particular, are recognized as relatively unpredictable arts.

93. During prosecution of the patent, the patentee acknowledged that it was improper to hold that chemical structures generally obviated another chemical structure.

94. The description of two ways of making a controlled release bupropion composition is insufficient to justify a grant of a patent covering all pharmaceutical means of controlling the release of bupropion, which would include those yet to be discovered only after arduous experimental efforts.

95. GSK purposefully obfuscated the patent application during prosecution to obtain a patent monopoly covering more than was invented.

96. By claiming more than GSK was entitled to, the patent discouraged innovation in the field of controlled release pharmaceuticals since it would appear that one could expend great amounts of time and money to invent a novel excipient only to have it fall within the literal range of the '994 patent.

97. On July 26, 2000, EON submitted an ANDA for generic Wellbutrin SR containing a Paragraph IV certification that the '994 patent was invalid or not infringed by the EON pharmaceutical.

98. On November 29, 2000, GSK filed suit in the United States District Court for the Southern District of New York against EON, a generic drug manufacturer, for

infringing the '994 patent by submission of an ANDA proposing their marketing of a controlled release bupropion compound (the "EON II litigation").

99. By initiating this litigation, GSK received the 30-month stay preventing EON from marketing the generic Wellbutrin.

100. On January 24, 2002, EON received tentative approval for the generic Wellbutrin ANDA submitted on July 26, 2000.

101. The grant of tentative approval indicated that EON would have received final approval to begin marketing of generic Wellbutrin SR if not for the legal impediment of the then outstanding GSK litigation

102. On August 13, 2002 the United States District Court for the Southern District of New York invalidated the '994 patent for lack of enablement.

103. GSK not only knew at the onset of the EON II litigation that the '994 patent was nonenabled and therefore unenforceable, but in fact had written and prosecuted the patent in such a way as to attempt to capture patent protection for an invention it had not invented. GSK, however, still attempted to assert the faulty '994 patent in order to invoke the 30-month FDA stay, preventing a generic version of bupropion from coming to market and consequently, illegally extending their monopoly on Wellbutrin SR and its generic equivalents while the litigation progressed.

104. After the 30-month stay expired in November 2003, EON received final approval of the generic Wellbutrin SR ANDA from the FDA and announced that the product would be marketed. This announcement was made even though GSK

continued to prosecute the patent infringement litigation against EON.

105. GSK further delayed the introduction of EON's generic Wellbutrin SR by obtaining an injunction in the United States District Court for the Southern District of New York in November, 2003.

106. EON appealed the injunction to the Federal Circuit and it was stayed on January 14, 2004.

107. If not for the 30-month stay invoked by GSK filing the baseless EON II litigation and the additional period of exclusivity gained for GSK by obtaining an improper injunction, EON would have been able to market generic Wellbutrin on January 24, 2002, nearly two years earlier than they actually began marketing the drug.

CLASS ALLEGATIONS

108. Plaintiffs bring this action on their own behalf under Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to damages sought herein, as representatives of the Class defined as follows:

> All persons or entities in the United States that purchased Wellbutrin SR directly from GSK during the period of January 24, 2002 to a date to be determined.

Excluded from the Class are all governmental entities.

109. While the exact size of the Class is unknown to Plaintiffs at the present time, the members of the Class are numerous and geographically dispersed throughout the United States and joinder is impracticable.

110. Plaintiffs' claims are typical of the members of the Class, in that Plaintiffs

paid supracompetitive prices for Wellbutrin SR and purchased Wellbutrin SR from GSK.

111. Plaintiffs will fairly and adequately protect and represent the interests of the Class. The interests of Plaintiffs coincide with, and are not antagonistic to, those of the Class.

112. In addition, Plaintiffs' counsel are experienced and competent in the prosecution of complex class action antitrust litigation.

113. Questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members.

114. Questions of law and fact common to the Class include:

i. Whether GSK has illegally monopolized the market for Wellbutrin SR and its generic equivalents;

ii. Whether GSK's conduct caused sale prices of Wellbutrin SR to be at artificially high and non-competitive levels;

iii. Whether, and to what extent, GSK caused injury to the business or property of Plaintiffs and the Class and, if so, the appropriate measure of the damages.

115. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Among other things, class action treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of

evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

116. Plaintiffs know of no difficulty to be encountered in litigation of this action that would preclude its maintenance as a class action.

VIOLATION ALLEGED

117. Plaintiffs incorporate by reference the preceding allegations.

118. GSK violated Section 2 of the Sherman Act by defrauding the United States Patent and Trademark Office into issuing invalid patents and attempting to enforce invalid patents through sham litigation on which no reasonable litigant could have expected to prevail, solely to prevent low-cost generic versions of Wellbutrin SR from entering the market.

119. GSK violated Section 2 of the Sherman Act by using sham litigation alleging infringement under the DOE when no reasonable plaintiff could have expected a positive outcome on the facts of the case.

120. Plaintiffs and the Class have, as a consequence of GSK's anti-competitive behavior, sustained substantial losses and damage to their business and property in the form of paying prices for Wellbutrin SR that were higher than they would have been but for Defendant's monopolization and attempts to monopolize that product market in

the United States. The full amount of such damages is presently unknown and will be determined after discovery and upon proof at trial.

DEMAND FOR RELIEF

WHEREFORE, Plaintiffs respectfully request a judgment against GSK for the following relief:

1. Certification of the Class pursuant to Rule 23 of the Federal Rules of Civil Procedure, certifying Plaintiffs as the representatives of the Class, and designating their counsel as counsel for the Class;

2. A judgment for the damages sustained by Plaintiffs and the Class defined herein, and for any additional damages, penalties and other monetary relief provided by applicable law, including treble damages;

3. The costs of this suit, including reasonable attorneys' fees; and

4. Such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiffs demand a trial by jury.

Date: November ____, 2004

By:_____

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